

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>PCT 306</b>	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. <b>PCT/KR 2003/000665</b>	International filing date (day/month/year) <b>3 April 2003 (03.04.2003)</b>	Priority Date (day/month/year)
International Patent Classification (IPC) or national classification and IPC  <b>IPC<sup>7</sup>: C12N 15/87</b>		
Applicant <b>KOREA ADVANCED INSTITUTE OF SCIENCE AND TECHNOLOGY</b>		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examination Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>2</u> sheets.</p>	
<p>3. This report contains indications relating to the following items:</p> <p>I. <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II. <input type="checkbox"/> Priority</p> <p>III. <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV. <input type="checkbox"/> Lack of unity of invention</p> <p>V. <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI. <input type="checkbox"/> Certain documents cited</p> <p>VII. <input type="checkbox"/> Certain defects in the international application</p> <p>VIII. <input type="checkbox"/> Certain observations on the international application</p>	

Date of submission of the demand  <b>08.10.2004</b>	Date of completion of this report  <b>24 August 2005 (24.08.2005)</b>
Name and mailing address of the IPEA/AT <b>Austrian Patent Office Dresdner Straße 87 A-1200 Vienna Facsimile No. 1/53424/200</b>	Authorized officer  <b>MOSSER R.</b>  Telephone No. 1/53424/437

Form PCT/IPEA/409 (cover sheet) (July 1998)

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/KR 2003/000665

## I. Basis of the report

1. With regard to the elements of the international application:\*
  - ☐ the international application as originally filed
  - ☒ the description:
    - pages 1-13, as originally filed
    - pages \_\_\_\_\_, filed with the demand
    - pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_.
  - ☒ the claims:
    - pages claim 14, as originally filed
    - pages \_\_\_\_\_, as amended (together with any statement) under Article 19
    - pages \_\_\_\_\_, filed with the demand
    - pages 14 and 15 (claims 1-13), filed with the letter of 25 July 2005 (25.07.2005).
  - ☒ the drawings:
    - pages 1/8-8/8, as originally filed
    - pages \_\_\_\_\_, filed with the demand
    - pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_.
  - ☐ the sequence listing part of the description:
    - pages \_\_\_\_\_, as originally filed
    - pages \_\_\_\_\_, filed with the demand
    - pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_.
2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:
  - ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
  - ☐ the language of publication of the international application (under Rule 48.3(b)).
  - ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
  - ☐ contained in the international application in printed form.
  - ☐ filed together with the international application in computer readable form.
  - ☐ furnished subsequently to this Authority in written form.
  - ☐ furnished subsequently to this Authority in computer readable form.
  - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
  - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
4. ☐ The amendments have resulted in the cancellation of:
  - ☐ the description, pages \_\_\_\_\_.
  - ☐ the claims, Nos. \_\_\_\_\_.
  - ☐ the drawings, sheets/fig \_\_\_\_\_.
5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as „originally filed“ and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/KR 2003/000665**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

<b>I. Statement</b>			
Novelty (N)	Claims	1-14	YES
	Claims	----	NO
Inventive step (IS)	Claims	1-14	YES
	Claims	----	NO
Industrial applicability (IA)	Claims	1-14	YES
	Claims	----	NO

## Citations and explanations (Rule 70.7)

The following documents have been cited in the Search Report:

D1: US6221959B1  
D2: WO2000/040742A1  
D3: WO1998/059064A1  
D4: WO2002/043769A2  
D5: US5714166A

Considering the applicant's argumentation in conjunction with the amended application the examiner concurs in said applicant's view that claims 1-14 are new and represent an inventive step as compared with the disclosures of the documents cited in the search report.

D1 concerns compositions for stabilizing polynucleic acids and increasing the ability of polynucleic acids to cross cell membranes and act in the interior of a cell. In one aspect, D1 provides a polynucleotide complex between a polynucleotide and certain polyether block copolymers. The polynucleotide complex can further include a polycationic polymer, as well as suitable targeting molecules and surfactants. D1 also provides a polynucleotide complex between a polynucleotide and a block copolymer comprising a polyether block and a polycation block.

D1 concerns the compositions for intracellular delivery of nucleic acids, in which the methods of using polycations and their modified derivatives (with or without surfactant) for the formation of polynucleotide polymer complexes (100-200 nm). However, the present invention relates to direct conjugation of non-ionic hydrophilic polymers to oligonucleic acids, which can further be formulated with polycations to form small-size micelle-like particles. Those are polyelectrolyte complex micelles.

D2 pertains to a cellular transport system for the transfer of a nucleic acid through the nuclear envelope. The nuclear transport agent has a module which specifically binds

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V (page 1)

covalently to the terminal sequence of the DNA molecule. Said module comprises a synthetic peptide, a protein, a peptide nucleic acid, or a recombinant protein that specifically binds to the DNA molecule.

However, a synthetic peptide, a protein and a peptide nucleic acid are not considered as polymers in polymer chemistry. They are considered as macromolecules.

Therefore, D2 does not interfere with novelty and inventive step.

D3 deals with complexes of nucleic acid and polyethyleneimine (PEI), wherein PEI is modified with a hydrophilic polymer covalently coupled thereto. Claims 1 and 9 are not anticipated or obvious from D3. Thus, also the dependent claims 2-14 are not obvious from D3.

D4 concerns stable colloids containing an aqueous phase having suspended therein DNA. This is obviously not the subject-matter of present claims.

D5 concerns star polymers. From this document the subject-matter of the claims 1-14 is not obvious either.

Thus, novelty and inventive step are recognized for the subject-matters of the claims 1-14.

Industrial applicability is obvious for the subject-matters of all claims.